REMARKS

The present document is submitted in reply to the Office Action dated January 19, 2010 ("Office Action").

Applicants have amended the specification to incorporate sequence identifiers for the amino acid sequences shown in Figure 5. A substitute sequence listing is co-filed herewith to include certain of these amino acid sequences, which were inadvertently omitted from the original sequence listing.

Further, Applicants have amended claims 1, 3, 23, and 30 to more particularly point out the subject matter they deem as their invention. Support for the amendments appears in the specification at page 15, lines 14-19 and 24-29.[1] Applicants have also added new claims 38-53, support for which can be found in the specification at page 14, lines 15-20, page 16, line 15 through page 17, line 23; page 15, lines 9-12; and in Figure 5. Finally, Applicants have cancelled claims 2, 13-22, 24, 27, and 31-37, drawn to non-elected subject matter. These amendments have not introduced new matter.

Upon entry of the amendment, claims 1, 3-12, 23, 25, 26, 28-30, and 38-53 will be pending and under examination. Applicants respectfully request that the Examiner reconsider this application in view of the following remarks.

Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

The Examiner rejects claims 1, 3-12, 23, 25, 26, 28-30, 36, and 37 for lack of written description. See the Office Action, pages 2-3, items 4 and 5. As claims 36 and 37 have now been cancelled, only claims 1, 3-12, 23, 25, 26, and 28-30 are at issue.[2]

Claim 1 will be discussed first. The Examiner holds that the term "a functional equivalent thereof [of SET1]" recited in this claim lacks adequate description in the specification. See the Office Action, page 2, item 5, second paragraph.

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[1] The phrase "a fragment of the amino acid sequence that lacks only a signal peptide sequence as compared to the amino acid sequence," incorporated into claims 1, 3, 23, and 30, describes a mature SET1, i.e., a SET1 protein lacking any signal peptide sequence. The specification discloses mature SET1 proteins at page 15, lines 14-19. Thus, incorporation of this phrase into the claims has not introduced new matter.

[2] The Office Action indicates at page 1, item 4a, that claims 36 and 37 were withdrawn from consideration. Apparently, the Examiner erred in including these two claims as rejected for lack of written description.

Applicants have deleted the term at issue from claim 1. This claim, as amended, covers a method of isolating IgA in a sample using a SET1 polypeptide, which binds to IgA. This SET1 polypeptide contains (a) an amino acid sequence having at least 80% similarity to SEQ ID NO:1, or (b) a fragment of the amino acid sequence that lacks only a signal peptide sequence as compared to that amino acid sequence. SEQ ID NO:1 refers to a representative SET1 protein in precursor form (including a signal peptide sequence). See the specification, page 14, lines 12-20. Accordingly, (a) refers to a precursor SET1 sharing at least 80% sequence similarity to SEQ ID NO:1, and (b), a fragment of (a) that lacks only a signal peptide sequence, refers to a mature SET1. In short, amended claim 1 encompasses use of a SET1 polypeptide, at least a portion of which is a SET1 described in amended claim 1, either in precursor or mature form. This claim meets the written description requirement for the following reasons.

Amended claim 1 is akin to claim 2 in Example 11B of the Written Description Training Materials (hereinafter "Training Material").

Claim 2 in Example 11B is directed to a nucleic acid (SEQ ID NO:1) encoding a polypeptide that possesses activity Y. The specification in Example 11B discloses one example of the claimed nucleic acid and identifies two domains within the polypeptide encoded by the exemplary nucleic acid as essential to activity Y. In view of these teachings, the Training Material states:

> "those of ordinary skill in the art would expect that many of [ ] conservative substitutions would result in a protein having the required activity" and that "amino acid substitutions outside of the two identified functional domains are unlikely to greatly affect activity Y. ... Consequently, there is information about which nucleic acids can vary from SEQ ID NO:1 in the claimed genus of nucleic acids and still encode a polypeptide having activity Y."

The Training Material then proceeds to conclude that claim 2 meets the written description requirement.

Here, amended claim 1 covers a method of isolating IgA with a SET1 polypeptide capable of binding to IgA. As pointed out above, this SET1 polypeptide or a portion thereof is a SET1, either in precursor or mature form. The specification provides 11

examples of SET1, represented by SEQ ID NOs:1, 3-7, and 14-18. Further, it provides a sequence alignment of seven mature SET1 proteins and identifies conserved and variable residues in SET1. See Figure 5. Among these seven mature SET1 proteins, SSL7_NCTC6571 refers to the mature counterpart of SEQ ID NO:1, i.e., including residues 31-231 in SEQ ID NO:1 (residues 1-30 being a signal peptide, which, as a skilled artisan would know, plays no role in IgA binding). In view of these teachings, a skilled person in the art would readily know the residues within SEQ ID NO:1 that are essential to IgA binding, i.e., the conversed residues, and those that are not functionally important, i.e., the variable residues.

Pursuant to the above-quoted statement in the Training Material, a skilled artisan would expect that "conservative substitutions would result in a protein having the required activity" and that substitutions of residues other than these essential ones are unlikely to greatly affect the IgA binding activity of SET1. In other words, he or she would know which amino acid residues can vary from SEQ ID NO:1 without affecting SET1 activity. Indeed, compared to Example 11B, the present specification discloses many examples of the polypeptide/nucleic acid recited in the claim at issue, i.e., **11** exemplary SET1 polypeptides recited in amended claim 1 in this case *versus* **1** example of the nucleic acid recited in claim 2 of Example 11B. Following the conclusion in Example 11B, the present specification clearly provides adequate written description of the SET1 polypeptide for use in the method of amended claim 1.

In view of the above remarks, Applicants respectfully submit that amended claim 1 meets the written description requirement.

Claims 3-12, 23, 25, 26, and 28-30, like amended claim 1, also cover uses of the SET1 polypeptide recited in claim 1. For the same reasons set forth above, these claims meet the written description requirement as well.

Rejection under 35 U.S.C. § 103

The Examiner rejects claims 1, 3-12, 23, 25, 26, 28-30, 36, and 37 for obviousness over Fraser et al., a document including a presentation delivered by

Applicants at a conference on December 10, 2003. See the Office Action, pages 4-5, item 8. Note that previously withdrawn claims 36 and 37 have now been cancelled.

Applicants would like to point out that Fraser et al. is not citable prior art for the following reason:

As set forth in MPEP § 2141.01(I), "[a] 35 U.S.C. 103 rejection is based on 35 U.S.C. 102(a), 102(b), 102(e), etc. depending on the type of prior art reference and its publication or issue date." Here, Fraser et al. refers to a presentation delivered at a conference on **December 10, 2003**, within one year after the international filing date, i.e., **December 7, 2004**, of this US national application. Thus, it would be eligible as prior art only under 35 U.S.C. § 102(a).

The law is well settled that "one's own work is not prior art under § 102(a) even though it has been disclosed to the public in a manner or form which otherwise would fall under § 102(a)." In re Katz, 215 USPQ 14, 17 (CCPA 1982). Applicants submit herewith a declaration by co-inventor John David Fraser, stating that Fraser et al. merely discloses the inventors' own work. Pursuant to *Katz*, it does not constitute prior art under 35 U.S.C. 102(a).

In view of the above remarks, Applicants respectfully request withdrawal of this rejection, as it is based on non-citable prior art.

New Claims

New claims 38-41, 42-45, 46-49, and 50-53 depend from claims 1, 3, 23, and 30, respectively. For the same reason set forth immediately above, Fraser et al. is also not citable against these claims.

Further, all of the new claims require particular SET1 proteins represented by defined amino acid sequences. Without any ambiguity, these claims meet the written description requirement.

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The Petition for Extension of Time fee in the amount of $130 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges to Deposit Account No. 50-4189, referencing Attorney Docket No. 55502-012US1.

Respectfully submitted,

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